

Patient Information Leaflet for VICRYL™ Mesh

This leaflet has information about your implant. It does not contain all the information and if you have any questions, talk to your healthcare team. All implants have risks and benefits. Follow your healthcare team's advice even if it differs from what is in this leaflet. Please read this leaflet carefully and keep it in a safe place so you may refer to it in the future if needed.

The name and number of your mesh implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Product Codes: VKML, VKMM

Implant Description

VICRYL™ Mesh is made of a man-made material. It is the same material that is used in VICRYL™ sutures. It will help support your tissues while they heal.

It is a mixture of two polymers. One is called glycolide. The other is called L-lactide. It is the same material that is used in VICRYL™ Sutures. VICRYL™ Mesh is absorbed by the body.

VICRYL™ Mesh has a maximum weight per area of 800 mg per 100 cm².

Information for Safe Use

The selection of mesh for any given patient is a function of numerous factors including, but not limited to, the patient's past medical and surgical history, current medical condition (i.e., comorbidities), surgical technique, and size and location where temporary wound or organ support is required.

There is always a chance of adverse reactions with any type of surgery. Some reactions could be due to your overall health condition. Some reactions could be related to just having the surgery. Some reactions could be related to the materials being placed into the body. It is difficult to know the source of some adverse reactions. Contact your doctor about any signs of infection or adverse reactions. Be sure to keep up with your doctor visits after surgery.

This device will not cause any issues with a medical test called an MRI. MRI means magnetic resonance imaging.

Possible Adverse Reactions

Your doctor will provide information about the adverse reactions of your operation. All operations have adverse reactions. The risk of a serious adverse event is low. There is a risk that you may require additional operations or treatments for several reasons. Please talk to your doctor if you have concerns about your procedure.

Possible adverse reactions may include:

- Infection
- Inflammation (redness, swelling, pain, and feeling of heat)/foreign body sensation/reaction, local reaction, granuloma (a mass of tissue), seroma (a mass of clear fluid)

- Sudden, short-lasting pain and/or long-lasting pain
- Hematoma (bruising/a mass of blood)
- Impaired healing (delayed wound healing, adhesion (scar tissue joining two different surfaces), postprocedural fistula (an abnormal connection between organs), wound dehiscence (wound edges separating))
- Nerve Injury
- Soft tissue injury
- Extrusion (organ or product thrusting out of its preferred position)/Erosion (tissue injury progressing to tissue loss)
- Excessive contraction or shrinkage of the tissue surrounding the mesh,
- Mesh failure/hernia reoccurrence
- Treatment failure.

These adverse reactions may require additional operations or treatments. This list does not include all adverse reactions. Your doctor can further explain the adverse reactions of your operation.

Expected Implant Lifetime and Follow Up

VICRYL™ Mesh is compatible with your tissues while it is being absorbed. It still has about 80% of its strength after 14 days. It will be essentially absorbed within 90 days.

Reporting Adverse Reactions

If you wish to report any adverse reactions you believe are a result of your procedure implant, please speak with your doctor/medical team or report the information to Johnson & Johnson Medical Product Safety Department at productsafetyjjmanz@its.jnj.com or the Therapeutic Goods Administration at <https://www.tga.gov.au>

For access to this leaflet, please visit: <https://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets>

Sponsor

Johnson & Johnson Medical Pty Ltd

1-5 Khartoum Rd, North Ryde, NSW 2113

Tel: 1300 562 711